Medical Pharmacy Solutions Mandatory Site of Service Policy

Effective Date: January 1, 2026
Date of Origin: October 6, 2025

Background

The Medical Pharmacy Site of Service program directs members to the most cost-effective, clinically appropriate location to receive their infusion(s) of select specialty medications as listed in this policy. The site of care medical policy list is subject to change without prior notice.

Scope

Applicable to Commercial/Exchange membership

- New utilizers of these medications on or after January 1, 2026, will be subject to the program requirements.
- Members currently using these medications will be subject to the program requirements upon prior authorization renewal on or after January 1, 2026.

Program Requirements

- The Site of Service program requirements will be administered as part of the existing prior authorization program.
    - You may submit requests at GatewayPA.com via your Prime Therapeutics Medical Pharmacy provider portal account.
    - First-time users should select ***New Provider Access Request*** on the homepage to request access.
- All drugs in the Site of Service program require prior authorization.
- No age restrictions
- Requests for select specialty drugs as listed and to be administered in a hospital outpatient setting will be directed to a preferred alternative site of care, such as a non-hospital affiliated outpatient infusion (e.g., ambulatory infusion suite or a physician office) or home infusion. Infusions for these medications are excluded from payment when administered in a hospital outpatient infusion center.
- To prevent a delay in care and allow adequate transition time for members to an alternate infusion site, Site of Service program requirements will be waived for 60 to 150 days (depending on drug), after prior authorization approval so that members can transition to a different infusion site. After that time, infusions must be transitioned to lower cost site of care and will not be paid.

Drugs in Scope

Select infused specialty medications included in the Site of Service program are subject to change.

HCPCS	Brand Name	Generic Name
J3262	Actemra	Injection, tocilizumab, 1 mg
J0791	Adakveo	crizanlizumab
J1931	Aldurazyme	Injection, laronidase, 0.1 mg
J1426	Amondys 45	Injection, casimersen, 10 mg
J0225	Amvuttra	Injection, vutrisiran 25mg/0.5mL
J1554	Asceniv	Injection, immune globulin (asceniv), 500 mg
Q5121	Avsola	Injection, infliximab-axxq, biosimilar
J0490	Benlysta	Injection, belimumab, 10 mg
J0597	Berinert	Injection, c-1 esterase inhibitor (human), berinert, 10 units
J1556	Bivigam	Injection, immune globulin (bivigam), 500 mg
J2329	Briumvi	Injection, ublituximab-xiii
J1566	Carimune/Carimune NF Nanofiltered/ Gammagard S-D/IVIG	immune globulin, intravenous, lyophilized (e.g powder)
J1786	Cerezyme	Injection, imiglucerase, 10 units
J0717	Cimzia	Injection, certolizumab pegol, 1 mg
J2786	Cinqair	Injection, reslizumab, 1 mg
J0598	Cinryze	Injection, c-1 esterase inhibitor (human), (Cinryze), 10 units
J0584	Crysvita	Injection, burosumab-twza, 1 mg
J1555	Cuvitru	Injection, immune globulin (cuvitru), 100 mg
J1743	Elaprase	Injection, idursulfase, 1 mg
J3060	Elelyso	Injection, taliglucerase alfa, 10 units
J3380	Entyvio	Injection, vedolizumab, 1 mg
J3111	Evenity	Injection, romosozumab-aqqg, 1 mg
J1305	Evkeeza	Injection, evinacumab-dgnb, 5 mg
J1428	Exondys 51	Injection, eteplirsen, 10 mg
J0180	Fabrazyme	Injection, agalsidase beta, 1 mg
J0517	Fasenra	Injection, benralizumab, 1 mg
J1744	Firazyr	Injection, icatibant, 1mg
J1572	Flebogamma/DIF	Injection, immune globulin, (flebogamma/flebogamma dif), intravenous, non-lyophilized (e.g. liquid), 500 mg
J1569	Gammagard Liquid	Injection, immune globulin, (gammagard liquid), non-lyophilized, (e.g., liquid), 500 mg
J1557	Gammaplex	Injection, immune globulin, (gammaplex), intravenous, non-lyophilized (e.g. liquid), 500 mg
J1561	Gamunex-C/Gammaked	Injection, immune globulin, (gamunex-c/gammaked), non-lyophilized (e.g., liquid), 500 mg
J0223	Givlaari	Injection, givosiran, 0.5 mg
J1559	Hizentra	Injection, immune globulin (hizentra), 100 mg
J1575	Hyqvia	Injection, immune globulin/hyaluronidase, (hyqvia), 100 mg immunoglobulin

HCPCS	Brand Name	Generic Name
J0638	Ilaris	Injection, canakinumab, 1 mg
J3245	Ilumya	Injection, tildrakizumab, 1 mg
Q5103	Inflectra	Injection, infliximab-dyyb, biosimilar, (inflectra), 10 mg
J1290	Kalbitor	Injection, ecallantide, 1 mg
J2840	Kanuma	Injection, sebelipase alfa, 1 mg
J2507	Krystexxa	Injection, pegloticase, 1 mg
J0202	Lemtrada	Injection, alemtuzumab, 1 mg
J1306	Leqvio	Injection, inclisiran, 1 mg
J0221	Lumizyme	Injection, alglucosidase alfa, 10 mg
J3397	Mepsevii	Injection, vestronidase alfa-vjbk, 1 mg
J1458	Naglazyme	Injection, galsulfase, 1 mg
J0219	Nexviazyme	Injection, avalglucosidase alfa-ngpt, 4 mg
J2182	Nucala	Injection, mepolizumab, 1 mg
J2350	Ocrevus	Injection, ocrelizumab, 1 mg
J1568	Octagam	Injection, immune globulin, (octagam), intravenous, non-lyophilized (e.g. liquid), 500 mg
J0222	Onpattro	Injection, patisiran, 0.1 mg
J0129	Orencia	Injection, abatacept, 10 mg
J0224	Oxlumo	Injection, lumasiran, 0.5 mg
J1576	Panzyga	Injection, immune globulin, intravenous, non-lyophilized (e.g. liquid), not otherwise specified, 500 mg
J1459	Privigen	Injection, immune globulin (privigen), intravenous, non-lyophilized (e.g. liquid), 500 mg
J0897	Prolia/Xgeva	Injection, denosumab, 1 mg
J1301	Radicava	Injection, edaravone, 1 mg
J1745	Remicade	Injection, infliximab, excludes biosimilar, 10 mg
Q5104	Renflexis	Injection, infliximab-abda, biosimilar, 10 mg
J0491	Saphnelo	Injection, anifrolumab-fnia, 300 mg
J1602	Simponi Aria	Injection, golimumab, 1 mg, for intravenous use
J1299	Soliris	Injection, eculizumab, 10 mg
J3241	Tepezza	Injection, teprotumumab-trbw, 10 mg
J2356	Tezpire	Injection, tezepelumab-ekko, 1 mg
J2323	Tysabri	Injection, natalizumab, 1 mg
J1303	Ultomiris	Injection, ravulizumab-cwvz, 10 mg
J1427	Viltepso	Injection, viltolarsen, 10 mg
J1322	Vimizim	Injection, elosulfase alfa, 1 mg
J3385	Vpriv	Injection, velaglucerase alfa, 100 units
J3032	Vyepti	Injection, eptinezumab-jjmr, 1 mg
J1429	Vyondys 53	Injection, golodirsen, 10 mg
J9332	Vyvgart	Injection, efgartigimod alfa-fcab, 2mg
J1558	Xembify	Immune globulin (human)-klhw, 100 mg
J2357	Xolair	Injection, omalizumab, 5 mg

Exceptions

- Exceptions to the Site of Service program requirements are reviewed through the prior authorization process and may be granted on a case-by-case basis based on medical necessity.
- The administration of the infusion and injectable therapy referenced in this policy in a hospital outpatient setting is not considered medically necessary unless the criteria below are met:
    - Hospital outpatient administration of infusion or injectable therapy is considered medically necessary for up to a 60 to150-day period for members beginning a new treatment OR initial review of continuation of therapy.
    - An outpatient infusion or injectable therapy service in a hospital outpatient setting is considered medically necessary for the applicable validity period when any of the following are present (medical records required):
    - Potential changes in the member's clinical condition are such that immediate access to specific services of a hospital setting, having emergency resuscitation equipment and personnel, and inpatient admission or intensive care is necessary. For example, the member is at significant risk of sudden life-threatening changes in medical status based on clinical conditions including but not limited to:
        - Intolerable fluid overload, including impaired or unstable renal function; or
        - History of anaphylaxis to prior infusion therapy with a related pharmacologic or biologic agent despite standard pre-medication; or
        - Acute mental status/cognitive changes or physical impairment AND no home caregiver available; or
        - Vascular access not stable/member has significant documented venous access issues
        - Documented clinical history of cardiopulmonary conditions that may cause an increased risk of severe adverse reactions (including but not limited to thromboembolism, hypotension, seizures, aseptic meningitis syndrome, anaphylaxis, acute respiratory distress, pulmonary edema, apnea, and transfusion-associated lung disease); or
        - The member does not have access to home infusion AND the nearest office-based provider or ambulatory infusion suite, who can provide that service exceeds the travel distance of greater than 25 miles or more than 25 minutes average travel time to the currently-servicing hospital outpatient center; or
        - Home deemed unsafe environment for infusion (e.g., too many pets, esp. birds, aggressive dogs, etc.). The next requirement will be provider office; or
        - Patients are concurrently treated with another injectable medication covered under the patient's medical benefit that must be administered in a hospital setting; or
        - The prescribed medication has a site of administration restriction based on the FDA approved label; or
        - The member has received a bone marrow transplant (BMT) or chimeric antigen

receptor (CAR) T-cell therapy in the prior 6 months and requires enhanced medical supervision/monitoring at a specialized facility – documentation of the procedure/treatment must be submitted

- All other reasons for administering the infusion and injectable therapy services referenced in this policy in a hospital outpatient setting are not considered medically necessary.